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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,436	12/22/2004	Hilde Azjin	TIP0015 US	7541

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/519,436	AZJIN ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Preliminary Amendment, filed 22 December 2004, is acknowledged.

Claims 1-10 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 1, drawn to the special technical feature of a computer system comprising at least one database correlating the presence of at least one mutation in a human immunodeficiency virus (HIV) reverse transcriptase and a change in susceptibility of at least one strain of HIV to a reverse transcriptase inhibitor, comprising at least one record corresponding to a correlation between at least one mutation 194G in said reverse transcriptase, and treatment with at least a reverse transcriptase inhibitor.

Group II, claims 2 and 5, drawn to the special technical feature of a method comprising: (i) collecting a sample from an HIV-infected patient; (ii) determining whether the sample comprises a nucleic acid encoding HIV reverse transcriptase having at least one mutation 194G; (iii) correlating the presence of said at least one mutation of step (ii) to a change in effectiveness of said reverse transcriptase inhibitor or viral drug susceptibility.

Group III, claim 3, drawn to the special technical feature of a method comprising: (i) providing a HIV reverse transcriptase nucleic acid comprising at least one mutation 194G; (ii) recombining said nucleic acid of step (i) into a proviral nucleic acid deleted for said sequence to generate a recombinant HIV virus; (iii) determining a phenotypic response of said drug to said HIV reverse transcriptase; and (iv) identifying a drug effective against mutant HIV based on the phenotypic response of step (iii).

Group IV, claims 4 and 7, drawn to the special technical feature of a method comprising: (i) providing a HIV reverse transcriptase comprising at least one mutation

194G; (ii) determining the activity of said drug on said HIV reverse transcriptase; (iii) determining the activity of said drug on wild type HW reverse transcriptase; (iv) determining the ratio of the activity determined in step (iii) over the activity determined in step (ii); (v) identifying an effective drug against mutant HIV based on the ratio of step (iv).

Group V, claim 6, drawn to the special technical feature of a method comprising: (i) providing an HIV comprising a reverse transcriptase comprising at least one mutation 194G; (ii) determining a phenotypic response of said virus to said drug; and (iii) correlating the phenotypic response of step (ii) to a change in viral drug susceptibility.

Group VI, claim 8, drawn to the special technical feature of a vector for performing phenotypic analysis comprising an HIV sequence having at least one mutation 194G in the HIV reverse transcriptase.

Group VII, claim 9, drawn to the special technical feature of an isolated and purified HIV reverse transcriptase sequence having at least one mutation 194G, wherein said at least one mutation in said sequence correlates to a fold change in susceptibility towards a HIV reverse transcriptase inhibitor.

Group VIII, claim 10, drawn to the special technical feature of an isolated and purified oligonucleotide comprising a HIV reverse transcriptase sequence of 5 to 100 bases for *in vitro* diagnosis of viral drug resistance, characterized in that said oligonucleotide comprises at least one mutation 194G.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As set forth above, each group requires a special technical feature that is not present in any of the other groups.

Furthermore, the special technical feature in Group I is a computer system comprising at least one database correlating the presence of at least one mutation in a human immunodeficiency virus (HIV) reverse transcriptase and a change in susceptibility of at least one strain of HIV to a reverse transcriptase inhibitor, comprising

at least one record corresponding to a correlation between at least one mutation 194G in said reverse transcriptase, and treatment with at least a reverse transcriptase inhibitor. However, it is not an improvement over the prior art of Shafer *et al.* (Jan, 1999) and thus lacks an inventive step.

Shafer teaches the HIV RT and Protease Sequence Database with all published HIV reverse transcriptase sequences linked to data about the source of the sequence sample and the anti-HIV drug treatment history of the individual from whom the isolate was obtained (see entire document, in particular, Figure 2). The reference specifically teaches using the database for functional and clinical correlates of HIV reverse transcriptase sequence changes. See Medical Relevance.

Since Applicant's inventions are not a contribution over the prior art, they lack a special technical feature, they cannot be said to have unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Joint Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise Humphrey, Ph.D.
Patent Examiner
12 December 2005

JEFFREY STUCKER
PRIMARY EXAMINER